In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 20-0056V UNPUBLISHED

RHONDA ROSE.

Petitioner,

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: August 10, 2022

Special Processing Unit (SPU); Findings of Fact; Onset; Tetanus Diphtheria (Td) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Leigh Finfer, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Zoe Wade, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT AND DISMISSAL OF TABLE CLAIM¹

On January 16, 2020, Rhonda Rose filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleges that she suffered a left shoulder injury related to vaccine administration ("SIRVA") after a Td vaccine received on August 10, 2017. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

¹ Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, I find Petitioner's SIRVA Table claim must be dismissed, for failure to establish onset within the 48 hours following the administration of vaccination as required to establish a Table injury. This leaves a causation-in-fact claim that, if not promptly settled, will require adjudication outside of SPU.

I. Relevant Procedural History

On June 7, 2021, Respondent filed his Rule 4(c) Report stating that "this case is not appropriate for compensation under the [Vaccine] Act." ECF 24 at 2. Specifically, Respondent opposes compensation on the grounds that Petitioner has not established onset of her SIRVA within 48 hours of vaccination. *Id.* at 6. After reviewing the evidence, I subsequently ordered Petitioner to show cause as to why her Table SIRVA claim should not be dismissed. ECF 25 at 3. Petitioner filed her response on September 16, 2021, and Respondent filed a reply to Petitioner's response shortly thereafter. ECF 26, ECF 27.³ The matter is ripe for adjudication.

II. Issue

At issue is whether Petitioner's first symptom or manifestation of onset after vaccine administration (specifically pain) occurred within 48 hours as set forth in the Vaccine Injury Table and Qualifications and Aids to Interpretation ("QAI") for a Table SIRVA. 42 C.F.R. § 100.3(c)(10)(ii).

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally

_

³ I note that in their filings, both parties treated my order as requiring Petitioner to show cause as to why her entire case should not be dismissed. See ECF 26, ECF 27. However, the order clearly states that Petitioner should show cause "as to why her **Table claim** should not be dismissed." ECF 25 at 3 (emphasis added). Neither party focused on Petitioner's alleged failure to meet the "48-hour onset requirement" and instead addressed whether the claim should be dismissed entirely. Nevertheless, this ruling is limited in scope to a finding on that issue.

contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005).

However, the United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is also obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." La Londe, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); see also Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Finding of Fact

I make the following findings after a complete review of the record, including the filed medical records, affidavits, and Respondent's Rule 4 report:

- After suffering a burn on her foot, Petitioner received a Td vaccination in her left arm on August 10, 2017. Ex 1 at 1.
- On August 30, 2017, Petitioner visited Dr. Sarah Little, her primary care provider (PCP), with complaints of a "sinus problem." Ex 2 at 34. Petitioner did not report any shoulder pain and she was not diagnosed with a musculoskeletal condition at this appointment. *Id.* at 36.
- On September 19, 2017, Petitioner had an appointment with Dr. Kelly Cole, her rheumatologist, for follow-up treatment of ankylosing spondylitis. Ex 3 at 43. During the visit, Petitioner reported back pain, leg cramps, right foot burning, and stiffness in her legs and hips. *Id.* Dr. Cole performed a full physical examination that showed reduced range of motion of the cervical spine and lumbar spine tenderness; however, evaluation of the shoulders was normal. *Id.* at 46. Petitioner was diagnosed with ankylosing spondylitis and osteoarthritis of the bilateral knees; there is no shoulder-related diagnosis reflected in the records from this visit. *Id.* at 47.
- On September 26, 2017, Petitioner had an annual Medicare wellness exam with Dr. Little. Ex 2 at 39. The records from this visit do not reflect any complaints of shoulder pain, nor did Dr. Little diagnose Petitioner with any shoulder-related condition. *Id.* at 43-44, 46.
- On November 27, 2017, more than 15 weeks after vaccination, Petitioner returned to Dr. Little and made her first documented complaint of left shoulder pain. Ex 2 at 49. Petitioner stated that her shoulder pain "began in August after receiving [the] tetanus vaccine" at urgent care. *Id.* Physical examination of Petitioner's shoulder showed decreased range of motion and tenderness to palpation. *Id.* Dr. Little diagnosed Petitioner with "chronic left shoulder pain [that] began acutely after receiving [the] tetanus vaccination" and hypothesized that the vaccine "[m]ay have been administered too high resulting in shoulder bursitis." *Id.* at 50.
- Dr. Wallace Huff, an orthopedist, evaluated Petitioner on November 30, 2017. Ex 4 at 27. At this appointment, Petitioner reported left shoulder pain "ongoing for quite some time" that had "worsened over the last few weeks." Id. She denied any specific inciting injury or event. Id.
- The treatment records from Petitioner's visit with Dr. Cole on January 23, 2018, include a notation that Petitioner "ha[d] Tetanus shot [on 8/10/17] and developed shoulder pain after that has never resolved." Ex 3 at 37.

- On February 7, 2018, Petitioner had an initial physical therapy evaluation, at which time she reported that her pain "started after she received a tetanus shot" in her left shoulder. Ex 6 at 20.
- Petitioner alleges in her affidavit she began experiencing shoulder pain and stiffness the same day as her Td vaccination, but that she "just tried to deal with the pain for several months" before seeking formal treatment. Ex 9 at ¶¶ 4, 6.

The medical records do not corroborate Petitioner's statements regarding the onset of her shoulder pain occurring within hours of vaccination. In fact, Petitioner *acknowledges* that the records do not reflect complaints of left shoulder pain during the three intervening medical appointments. Ex 9 at ¶ 5. Instead, Petitioner avers that she mentioned her shoulder pain to Dr. Little at her appointments in August and September 2017, and that Dr. Little informed her that Td vaccinations "sometimes . . . are truly painful," but (Petitioner theorizes) these conversations were not documented in the record because her visits were primarily to address other conditions. *Id*. at ¶ 6.

However, at the time Petitioner received her vaccination, Dr. Little had been her PCP for almost two years, and her notes from each visit reflect a thorough discussion of Petitioner's complaints, examination findings, diagnoses, and instructions for future visits. Ex 2. Furthermore, while Petitioner's August 2017 appointment with Dr. Little was a "sick visit" focused on her sinus problems, the notes from her September 2017 appointment reflect a discussion of numerous conditions, including the pain caused by Petitioner's ankylosing spondylitis. Ex 2 at 43. Given these facts, it is unlikely that Dr. Little would not have at least noted Petitioner's reports of left shoulder pain even if the "plan" had been to wait to see if it resolved, as Petitioner has alleged.⁴

Additionally, even if Petitioner made an undocumented reference to her shoulder pain at her appointments with Dr. Little, Petitioner has not provided an explanation as to why there is no mention of shoulder pain in the records from her September 2017 visit with Dr. Cole, the rheumatologist who has been treating Petitioner since 2014. Dr. Cole's

(Fed. Cir 2021) (medical records are based on the statements made by patients regarding the symptoms they are experiencing, and such records may serve as corroborating evidence for evaluating credibility).

⁴ See Sanchez v. Sec'y of Health & Human Servs., No. 11-685V, 2013 WL 1880825, at *2 (Fed. CI. Spec. Mstr. Apr. 10, 2013), vacated on other grounds, Sanchez by & through Sanchez v. Sec'y of Health & Human Servs., No. 2019-1753, 2020 WL 1685554 (Fed. Cir. Apr. 7, 2020) (presumption that contemporaneously generated medical records are probative "is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions") (emphasis added); James-Cornelius v. Sec'y of Health & Human Servs., 984 F.3d 1374, 1380

detailed notes from this visit reflect a thorough physical examination with abnormalities noted only in the cervical and lumbar spine and no tenderness, swelling, or limited range of motion in the shoulders. Ex 3 at 46. The records further reflect that Petitioner had to stop taking one of her medications while waiting for the burn on her foot to heal, yet despite this discussion of the precipitating event for vaccination, there is no evidence that Petitioner mentioned the Td vaccination or any subsequent shoulder pain at this visit with Dr. Cole. *Id.* at 43.

Moreover, while Petitioner maintains that the onset of her pain occurred within hours of vaccination, her treatment records consistently make generalized references to her shoulder pain beginning after vaccination without specifying a more precise onset. See, e.g., Ex 2 at 49; Ex 3 at 37; Ex 6 at 20. Additionally, during her first appointment with Dr. Huff, Petitioner denied any specific inciting injury or event. Ex 4 at 27. While such language certainly supports a finding that Petitioner began experiencing left-sided shoulder pain *some time* after vaccination, it does *not* support a finding that she more likely than not suffered onset of her condition within 48 hours.⁵

Finally, Petitioner's treatment history is inconsistent with her allegations regarding the severity of her symptoms. As a general matter, "[i]t is reasonable to expect that the average Program claimant might seek medical treatment sooner if in fact the person was experiencing sudden post-vaccination pain." Pitts v. Sec'y of Health & Human Servs., 18-1512V, 2020 WL 2959421, at *5 (Fed. Cl. Spec. Mstr. Apr. 29, 2020). As noted above, Petitioner averred in her affidavit that her shoulder "became very painful and stiff" only hours after vaccination. Ex 9 at ¶ 4. Further, Petitioner has described her pain as "constant" and "aching/burning," first located within the upper arm and deltoid region and later radiating down her arm, across her chest, and into her neck, which caused difficulty "raising [her] arm, lifting weight, [and] reaching back" and interfered with her sleep and ability to perform activities of daily living. Ex 2 at 47; Ex 6 at 20. Given the alleged severity of Petitioner's symptoms, it would be reasonable to expect that she would have sought out some intervention for her left shoulder, especially since she had access to a doctor who was treating her pain caused by other conditions. Instead, Petitioner did not complain of shoulder pain severe enough to warrant mention in the medical records until 15 weeks after vaccination. In some cases, this would merely constitute a limitation on damages to be awarded (specifically pain and suffering) - but here it further undermines the contention that the shoulder pain was in fact as sudden as alleged.

I acknowledge that the standard applied to SIRVA claims on the onset issue is fairly liberal. Even in the absence of direct proof, that standard will often permit a determination that onset began within the 48-hour timeframe set by the Table, based on records prepared a few months after vaccination, and/or corroborated by sworn witness

⁵ See Bulman v. Sec'y of Health & Human Servs., 19-1217V, 2021 WL 4165349, at *4 (Fed. Cl. Spec. Mstr. Aug. 12, 2021).

statements intended to amplify otherwise-vague records. There are many situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *DeGeorge v. Sec'y of Health & Human Servs.*, 18-1815V, 2021 WL 2433250, at *6 (Fed. Cl. Spec. Mstr. May 13, 2021); *Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006); *Lowrie*, 2005 WL 6117475, at *19. But not every SIRVA claim can be so preponderantly established, and certainly not where the sequential and contemporaneous record does not lend overall support to the Petitioner's allegations.

Therefore, after considering the record as a whole, I find there is not preponderant evidence to establish that Petitioner suffered the onset of symptoms within 48 hours of her Td vaccination as required by the Vaccine Injury Table. 42 C.F.R. § 100.3(a)(I)(C). However, I also note that the other Table indicia of a valid SIRVA claim *do* seem to exist – meaning that this is likely a viable non-Table claim even if Table onset cannot be proven. To that end, I urge the parties to make one final brief attempt at settlement.

V. Scheduling Order

Petitioner has not preponderantly established that onset of her pain occurred within 48 hours of vaccination. Accordingly, Petitioner's Table SIRVA claim is dismissed. **The parties shall file a final settlement status report on or before Monday, September 12, 2022**. The matter shall be transferred thereafter if the parties do not report significant progress in reaching an agreement at that time.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master